Message

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]
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To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: Yesterday
Attachments: IRIS Aug 29-30 SAB CAAC 8_30_2017 V3.pptx

Richard,
See our slides attached. I have pasted **two** BNA articles below:

Risk Assessment
EPA Chemical Analysis Program's Science Focus of Sept. 6 Hearing

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Snapshot

• House Science subcommittees schedule Sept. 6 hearing on central EPA chemical toxicity analysis program
• EPA science advisors back changes IRIS program has made, direction it's headed

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By Pat Rizzuto

EPA's chemical toxicity program will be at the forefront of a House Science Committee hearing Sept. 6.

Two subcommittees of the House Committee on Science, Space, and Technology, one on environment and another on oversight, will hold the hearing. It will focus on the Environmental Protection Agency's Integrated Risk Information System (IRIS), which analyzes the human health harms that chemicals may cause and the doses at which those harms could manifest.

The National Academies, Government Accountability Office, American Chemistry Council, and others have criticized the IRIS program for years. They have said it takes too long to evaluate chemicals and that the program's rationale for many decisions isn't clear.

The academies, however, praised recent improvements the EPA has made to the IRIS program. The EPA's Science Advisory Board, which met Aug. 30, decided it will send a letter soon to EPA Administrator Scott Pruitt to show its support for the renewed IRIS program.

Kenneth Mundt, director of applied epidemiology for the consulting group Ramboll Environ, and former Dow Chemical Co. toxicologist James Bus, now a senior managing scientist at Exponent, will testify. Both scientists and those consulting firms have long worked for or on behalf of various chemical and tobacco companies as well as for trade associations. Bus also has directed four toxicological associations, including the Society of Toxicology.

Thomas Burke, who served as EPA's science advisor and deputy assistant administrator for research and development under former President Obama, will testify at the invitation of committee Democrats. Burke is an environmental and public health professor at Johns Hopkins University.

Formaldehyde Likely Issue

Questions about the IRIS program's formaldehyde assessment are likely to arise at the hearing.

In May, Mundt published a critique of a study on occupational exposure to formaldehyde. That study was critical in the EPA's IRIS program, National Toxicology Program, and International Agency for Research on Cancer's analyses of formaldehyde's cancer-causing potential and link to leukemia and related cancers. Mundt's analysis concluded the workers study did not support a link between formaldehyde exposure and leukemia.

The IRIS program's formaldehyde assessment, launched more than a decade ago, has not been completed. A 2011 critique that the National Academies of Sciences, Engineering, and Medicine issued about the EPA's draft formaldehyde assessment was one of the central motivations for the agency to revamp IRIS.

The academies did not oppose the EPA's proposed conclusion that formaldehyde could cause leukemia and other cancers, but it urged the agency to better support that conclusion as well as other key conclusions.

To contact the reporter on this story: Pat Rizzuto in Washington at prizzuto@bna.com

To contact the editor responsible for this story: Rachael Daigle at rdaigle@bna.com

For More Information

The hearing announcement is available at http://src.bna.com/r8t

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Risk Assessment

EPA Rapidly Revamping Chemical Risk Reviews to Dodge Cuts

Snapshot

- EPA accelerating IRIS program with behind-the-scenes changes
- Science Advisory Board to send letter of support to Pruitt

By Sylvia Carignan

The EPA's chemical toxicity assessment program is sprinting toward innovation to avoid the administrator's chopping block.

After years of criticism and attempted reforms, the Environmental Protection Agency is overhauling the Integrated Risk Information System with a raft of behind-the-scenes changes. Though the agency's scientific advisers like what they see, it's unclear whether those changes can satisfy the program's critics and help regulators by speeding up risk assessments and increasing transparency.

The EPA's National Center for Environmental Assessments houses the Integrated Risk Information System, also known as the IRIS program, which analyzes the human health harms that chemicals may cause and the doses at which those harms could manifest. The analyses are used in setting exposure limits and other health protections.

"We're trying to shape the future of risk assessment, whether it's in the human health arena or the environmental health arena," Tina Bahadori, who leads the center, which synthesizes new scientific information about chemicals into reports that help the agency set regulations and limits, said at a Science Advisory Board meeting Aug. 30.

The board intends to send a letter to EPA Administrator Scott Pruitt to show its support for the renewed IRIS program.

In response to a board member who asked how the center will accomplish its goals so quickly, Bahadori said she and her colleagues are motivated by the fact that their center's "mere existence is at risk." In March, the president's fiscal year 2018 budget request proposed to eliminate IRIS, although the final budget request included it.

The House Committee on Science, Space, and Technology will meet Sept. 6 to discuss the IRIS program.

"This is extraordinary, and we would not want to see this effort stopped or hindered," said board member Gina Solomon, a deputy secretary at the California Environmental Protection Agency. "Coming from a state perspective, I know the value of the IRIS numbers. We rely on them quite often and there's not another entity that provides that function."

Accelerating Reviews

The proposed changes to the program include:
• emphasizing systematic reviews;
• creating "interim deliverables" to finalize and publish parts of an assessment instead of delaying publication for a single controversial section;
• training select employees on new tools and farming out their expertise to the rest of the center and the agency;
• determining which chemicals may be future risks and preparing resources accordingly; and
• working with risk assessors internationally to identify opportunities for innovation.

Hurdles to Clear

Bahadori said that the IRIS program's challenges are not unique.

"Assessments are complicated to do," she said. "Risk assessments are becoming very nuanced, very expert-driven and very controversial."
Kenneth Ramos, a member of the Science Advisory Board and associate vice president for Precision Health Sciences at the University of Arizona, said the center is moving "at the speed of light," but the rest of the field may not catch up.

"Risk assessment, like medicine, is slow and cranking, and so it takes time for change to be adopted," he said at the board meeting. By moving too quickly, Ramos said, the center may risk leaving its audience, including the chemical industry and policymakers, in the dust.
Bahadori said the center plans to "bring the real live risk assessors along with us and make sure we have buy-in and support."

Members of the chartered Science Advisory Board include consultants, researchers and analysts at U.S. universities, environmental advocacy groups, Dow Chemical, Procter & Gamble, and Exxon Mobil Corp.

—With assistance from Pat Rizzuto.
To contact the reporter on this story: Sylvia Carignan in Washington at scarignan@bna.com
To contact the editor responsible for this story: Rachael Daigle at rdaigle@bna.com